PATENT SPECIFICATION

648,522

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COMPLETE SPECIFICATION

Improvements in or relating to a Container

I, ARTHUR HAROLD STEVENS, a British Subject, of the Firm of Stevens, Langner, Parry & Rollinson, Chartered Patent Agents, of 5—9, Quality Court, Chancery Lane, London, W.C.2, do hereby declare the nature of this invention (a communication from Baxter Laboratories, Inc., a corporation organised under the laws of the State of Delaware, United States of America, of Village of Morton Grove, State of Illinois, United States of America), and in what manner the same is to be performed, to be particularly described and ascertained in and by the following statement:—

This invention relates to a container and closure means therefor, and more particularly to a container adapted to be employed in the withdrawal and dispensing of blood and blood portions. The invention also relates more specifically to a container closure and to a method of withdrawing and dispensing blood and other fluids.

An object of the invention is to provide for aseptically and efficiently handling biologic materal, such as, for example, blood, blood plasma, blood serum and similar materials. A further object is to provide a container adapted to be employed as a phlebotomy unit and as a means for dispensing blood or portions thereof without transfer to another container.

A further object is to provide a container adapted for the use of parenteral and other fluids and solutions, permitting the collection and dispensing of the same. Other specific objects and advantages will appear as the specification proceeds.

The invention is illustrated, in preferred embodiments, by the accompanying drawings, in which:—

Fig. 1 is a vertical sectional view, partly broken away, showing a container and closure embodying my invention; Fig. 2 is a similar view showing a rubber sealing disk upon the closure and an inlet needle extending therethrough; and Fig. 3 is a similar view showing the unit connected for the dispensing of fluids therefrom.

In the illustration given, A designates a container; and B, a closure plug therefor.

The container A may be of any suitable structure. In the illustration given in Fig. 1, the container is provided with an internal bead 10 upon which the plug B rests.

The plug B consists of resilient rubber or other suitable resilient sealing material. It is provided with a liquid flow passage 11 and an air inflow passage 12. It will be noted that each of the passages 11 and 12 is constricted toward its top portion. Above passage 11 but separated therefrom by a thin diaphragm 13 is a depression 14 which, in effect, provides a continuation of the upper portion of passage 11. Above the upper portion of passage 12 is a depression or passage 15 separated from passage 11 by a thin diaphragm 16. It will be understood that the diaphragms 13 and 16 are readily formed within the passages by molding tools and provide accurately dimensioned films or diaphragms which provide an air-tight seal.

The diaphragms 13 and 16 are very thin and are not self-sealing when punctured with a hypodermic needle. These diaphragms are adapted to be punctured to permit the introduction into the respective passages closed by the diaphragms of an air inlet tube and a fitting for dispensing liquid.

The plug B is also equipped with a passage 25 which extends through only a portion of the plug. The portion of the plug above this passage 25 indicated at 25^a provides a thick resilient diaphragm which is preferably three times as thick as said diaphragms 13 and 16. The diaphragm 25^a when punctured with a hypodermic needle of a diameter of 1/12 the

[*Price* 2/-]

thickness of said diaphragm is self-sealing on the withdrawal of the needle.

A sealing disk 22 may be placed over the top surface of the plug B in order to maintain the upper surface of the plug in sterile condition. This disk may be maintained in position by a clamp device 23 which engages one of the external beads on the neck of the container and the top portion of the disk 22. The sealing disk 22 is preferably formed of a resilient material such as rubber, so that a needle may be inserted therethrough.

As seen in the drawing, it is important for effective operation of the self-sealing diaphragm 25^a that at least one of the passages 11 and 12 be disposed immediately adjacent the passage 25 so that the wall of the passage 25 serves to separate the two passages. The separating wall should be thin and resilient so that when downward pressure is exerted on the thick diaphragm in puncturing the same with a needle, the wall of the passage 25 flexes into the adjacent passage.

In the operation of the device, the container may be partially evacuated and sealed by placing the plug B loosely within the neck of the container while the container is evacuated. If desired, the plug may be slightly tilted within the neck. Air is withdrawn through the passages provided by the loose fitting of the plug within the container. The plug may be seated in sealing position by the sudden change of the pressure to atmospheric pressure or by being pressed into position within the neck of the container. In any event, the passages 11, 12 and 25 are sealed by the diaphragms 13, 16 and 25^a respectively.

When the container is evacuated and the plug placed in sealing position, the container may be capped with or without a disk between the cap and the plug.

When the unit is to be used in a blood transfusion operation, a needle 26 (Figure 2) is passed through the resilient sealing disk 22 and the integral self-sealing diaphragm 25^a. The needle 26 communicates with a valve 27 and tube 28 through which blood flows. The blood is drawn into the container under the influence of vacuum within the container.

When the blood is received within the container, the needle is withdrawn from the diaphragm 25^a and the opening formed by the needle in this diaphragm is closed. The diaphragm, by reason of its thickness and resiliency and the arrangement of a passage adjacent the passage 25 into which the wall of the passage 25 may flex, is self-sealing. At the same time, the resilient seal 22 provides a sterile top surface for the plug. The container with its supply of blood hermetically sealed therein may now be banked until it is desired to use the blood.

When the blood is to be dispensed, the resilient sealing disk 22 is removed to provide a sterile top surface for the plug B. The blunt end of a fitting 19 (Figure 3) is then pressed through the thin diaphragm 13 to bring the lower head 20^a of the fitting against the lower shoulder of the passage 11. If desired, the diaphragm 13 may be slightly punctured with an instrument before introducing the fitting 19. The diaphragm 13 tightly engages the neck of the fitting and tends to draw the fitting upwardly so as to urge the lower head 20^a of the fitting tightly against the shoulder of the passage 11. The flexible material of the diaphragm 13 thus cooperates with the shoulder 13^a to maintain the fitting in effective sealing relation with the plug B. The shoulder 13^a is preferably spaced below the diaphragm 13 by a distance at least as great as the radius of the diaphragm. Air and particles within the passage above the shoulder are prevented from entering the container, and liquid within the container is prevented from escaping about the fitting in the withdrawal operation. As is customary, the container is inverted in the withdrawal operation and suspended by means of a bail (not shown). The diaphragm 16 is punctured with the needle 17 to permit air to enter the container as the liquid flows therefrom. The fitting may contain a filter drip device 20 of wellknown construction, which in turn communicates with a dispensing tube 21.

To facilitate the passing of the needle through the thick diaphragm 25, the top of the diaphragm may be provided with an integral molded mark, such as an "X," thus indicating where the needle is to be pressed into the plug.

When the hypodermic needle is pressed downwardly against the self-sealing diaphragm 25, this resilient diaphragm is flexed downwardly at the portion thereof (normally the center portion) engaged by the needle. In the present construction, the arrangement of the passages, so that the first passage which is closed by the self-sealing diaphragm is separated from the other passages by the resilient wall of the first passage, permits the resilient wall to flex into the free area in the central longitudinal portion of the additional passages when pressure is exerted upon the self-sealing diaphragm. Thus, when the self-sealing diaphragm is to be punctured by the hypodermic needle, the downward pressure of the needle on the upper surface of the diaphragm causes the plug about the walls of the passage at the

upper portion thereof to be drawn inwardly and the central longitudinal portion of the walls of this passage to flex outwardly into the free areas provided by the adjacent passages. The thick diaphragm is punctured when in this position. After the needle is withdrawn, the resilient walls of the passage spring back to their original position and tend to urge the punctured portion of the diaphragm upwardly to increase the effectiveness of the seal therein.

The apparatus is suitable for the dispensing of any blood portion, such as whole blood, blood plasma, blood serum, etc. It will be understood that after the blood is collected in the container A, it may be centrifuged or allowed to stand to bring about a separation of the formed elements from the liquid portion. In the dispensing operation, the portions may be withdrawn separately or dispensed entirely as a whole blood.

Although the invention has been described in connection with certain specific embodiments, it will be apparent that modifications and changes may be made without departing from the spirit and scope of the invention.

Having now particularly described and ascertained the nature of my said invention and in what manner the same is to be performed, I declare that what I claim is:—

1. A container including closure means for said container comprising a resilient plug engaging an open neck of the container in sealing relation therewith, said plug being provided with a passage extending therethrough, a thick integral resilient diaphragm extending across the upper portion of the passage to close the same, said diaphragm, after being punctured with a hypodermic needle, being self-sealing against the passage of air therethrough when the interior of said container is under vacuum, said plug being provided with an additional passage separated from said first-mentioned passage by the resilient wall thereof, said additional passage providing an area into which said wall is adapted to flex when pressure is exerted on said thick diaphragm in puncturing the same with said needle, and a thin integral resilient diaphragm, substantially non-resistant to lateral flexing, extending across said additional passage to close the same, said thin diaphragm, when punctured by a hypodermic needle, being non-self-sealing against the passage of air when the interior of said container is under vacuum.

2. A container according to claim 1, wherein said additional passage provides a free area in the central longitudinal portion thereof into which said wall is adapted to flex against the resilience thereof when pressure is exerted on said thick diaphragm in puncturing the same with said needle, the resilience of said wall urging the punctured portion of the thick diaphragm upwardly, after the needle is withdrawn therefrom, to increase the effectiveness of the seal in said thick diaphragm.

3. A container according to claim 1, wherein said plug is provided with a pair of additional passages, each of said additional passages being separated from the first passage by the resilient wall thereof, said additional passages providing areas into which the wall of said first passage is adapted to flex when pressure is exerted on said thick diaphragm in puncturing the same with said needle.

4. A container according to claim 2 or 3, wherein the thin integral resilient diaphragm extends across the upper portion of said additional passage or each of said additional passages to close the same.

5. A container according to claim 1, wherein said thick diaphragm is of a thickness at least three times as great as the thickness of each of said thin diaphragms.

6. A container according to claim 1, wherein said thick diaphragm, after being punctured with a hypodermic needle of a diameter of approximately one-twelfth the thickness of said diaphragm, is self-sealing against the passage of air therethrough when the interior of the container is under vacuum.

7. A container according to claim 1, wherein said thin diaphragm is puncturable to permit the insertion of an outlet tube in the additional passage, and the plug is equipped with a shoulder in said additional passage for engaging an enlarged portion of the outlet tube.

8. A container according to claim 7, wherein the plug forms in said passage a constricted portion of substantially uniform diameter with a shoulder in an intermediate portion of said passage and at the bottom of said constricted portion for engaging an enlargement on the outlet tube to retain the outlet tube within the passage.

9. A container according to claim 7, wherein the plug is equipped with a constricted portion in said passage below said thin diaphragm and a shoulder at the bottom of the constricted portion and above the bottom surface of the plug for engaging an enlarged portion of the outlet tube to retain the outlet tube within the passage, said shoulder being spaced below said diaphragm by a distance at

least as great as the radius of the diaphragm.

10. A container including closure means for said container comprising a resilient plug engaging an open neck of the container in sealing relation therewith, said plug being provided with a pair of passages extending therethrough, each of which is closed in its upper portion by a thin integral diaphragm, said plug having its bottom portion cut away at a point generally between said openings to provide a thick diaphragm, said diaphragm, after being punctured with a point-equipped tube, being self-sealing against the passage of air therethrough when said tube is withdrawn, and a resilient flexible sealing member extending across the top wall of said plug and adapted to form an indentation above either of said passages under the influence of vacuum within said container if either of said diaphragms should be broken.

11. A container constructed substantially as herein described with reference to the accompanying drawings.

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[This Drawing is a reproduction of the Original on a reduced scale.]

Fig. 1

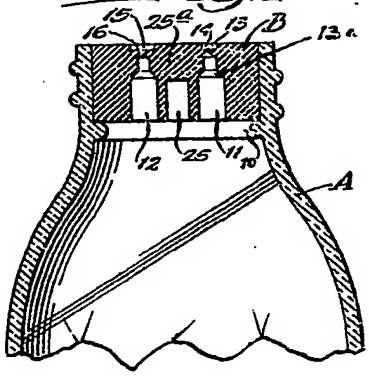


Fig. 3

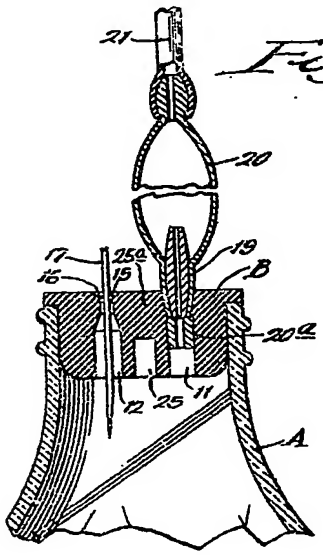
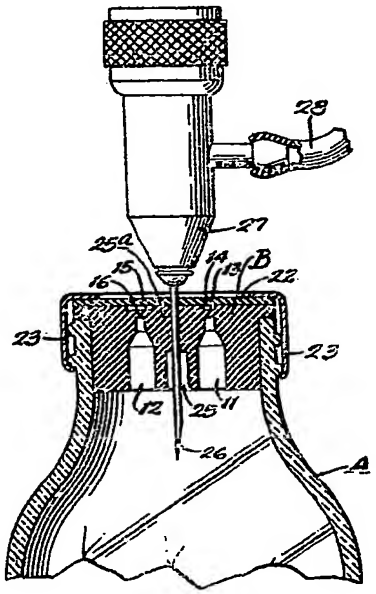


Fig. 2



H.M.S.O. (Ty. P.)